SCHERING CORPORATION

GALLOPING HILL ROAD KENILWORTH, N. J. 07033

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#31

May 27, 1997

Assistant Commissioner for Patents
Box Patent Extension
Washington, D.C. 20231
Attn: Special Program Law Office

RE: Request for reconsideration:
Patent Term Extension Application
for U.S. Patent No. 4,634,697
for CEDAX® (Oral Suspension)
FDA Docket No.: 96E-0099

Sir:

Schering Corporation ("Applicant" or "Schering") respectfully requests reconsideration of the PTO Notice of Final Determination, dated April 25, 1997 (enclosed), in the above-referenced application. Specifically, Schering takes issue with the conclusion in the aforesaid Notice that Schering's election to have U.S. Patent No. 4,812,561 ("the '561 patent") extended renders U.S. Patent No. 4,634,697 (the '697 patent) ineligible for extension, despite the fact that the '697 patent meets all the statutory requirements for extension. The Schering request for reconsideration of the aforesaid Notice of Final Determination with respect to the '697 patent is without prejudice to the Schering election, filed on this date under separate cover, to have the '561 patent extended (FDA Docket No. 96E-0100).

Both the '697 patent and the '561 patent claim the human drug product CEDAX® (active ingredient: ceftifubten dihydrate). CEDAX® was the subject of **two separate regulatory review periods**, one for a capsule product (NDA No. 50-685), and one for an oral suspension product (NDA No. 50-686). The regulatory review period for the capsule product commenced on August 1, 1987; and the regulatory review period for the oral suspension product commenced on September 28, 1988. Both regulatory review periods ended on the same day, and the FDA granted permission for commercial marketing or use for both products in a letter to Schering dated December 20, 1995 (Exhibit VII of the above-referenced application). Accordingly, Schering filed one application for patent term extension for each of the

'561 patent and the '697 patent based on each of the two separate regulatory review periods, for a total of four patent term extension applications.

Although all of the Notices of Final Determination on these applications suffer from the same flaw, namely that they all failed to acknowledge that there were two separate regulatory review periods for the two CEDAX® products, Schering is specifically requesting extension of the '697 patent based on the regulatory review period for the CEDAX® oral suspension product and therefore requests reconsideration of the PTO's requirement in each of the Notices of Final Determination that Schering elect a single patent and a single review period. For example, in the Notice of Final Determination for the '697 patent based on the regulatory review period for the CEDAX® oral suspension product, the PTO found that (1) the '697 patent is eligible for patent term extension under 35 U.S.C. § 156; (2) the period of extension is to be five years; and (3) the expiration date after extension will be October 1, 2009. Nevertheless, the aforesaid Notice of Final Determination also concluded that only one of the '561 patent or the '697 patent may be extended on the basis of either of the two regulatory review periods. Because Schering has elected to extend the '561 patent term on the basis of the CEDAX® capsule regulatory review period, the aforesaid Notice of Final Determination precludes Schering from extending the '697 patent term on the basis of the CEDAX® oral suspension regulatory review period.

In support of its conclusion, the PTO in the aforesaid Notice of Final Determination cites 35 U.S.C. §§ 156(c)(4) and 156(a)(5). Section 156 (c)(4) provides that "in no event shall more than one patent be extended...for the same regulatory review period for any product" 35 U.S.C. §156 (c)(4) (emphasis added). As discussed above, the regulatory review periods for the CEDAX® capsule product and the CEDAX® oral suspension product are **different**, and Schering has elected, in a letter filed today under separate cover, to extend the '561 patent based on the regulatory review period for the CEDAX® capsule product. Accordingly, the regulatory review period for the oral suspension product may properly form the basis for extending the term of the '697 patent without violating Section 156 (c)(4), and Schering has also elected to extend the '697 patent on that basis.

Section 156(a)(5) requires that "the permission for commercial marketing or use of the product after [the] regulatory review period is the first permitted commercial marketing or use of the product...." 35 U.S.C. §156 (a)(5). In this case, the first permitted commercial marketing or use of the CEDAX® product was granted by the FDA in its December 20, 1995 letter, which approved use of CEDAX® in both its capsule and oral suspension forms. Thus, a straightforward application of §156 (a)(5) provides no basis for denying the Schering request that the '697 patent be extended on the basis of the CEDAX® oral suspension regulatory review period--it is undeniable that "the permission for commercial marketing or use of the product" after that regulatory review period was "the first permitted commercial marketing or use" of the CEDAX® product.

For the foregoing reasons, Schering urges reconsideration, withdrawal of the requirement to elect a single patent and a single regulatory review period, and a favorable decision on the Schering request for extension of the term of U.S. Patent No. 4,634,697 based on the CEDAX® (oral suspension) regulatory review period.

A duplicate original copy of this letter transmitted today by telefax is being deposited First Class mail in an stamped envelope addressed to the Assistant Commissioner for Patents, Box Patent Ext., Washington, D.C. 20231
Attn: Hiram H. Bernstein.

Respectfully submitted,

Thomas D Hoffman

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PATENT DEPT. K-6-1 1990
SCHERING-PLOUGH CORPORATION
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U.S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO ASSISTANT COMMISSIONER FOR PATENTS, * WASHINGTON D.C. 20231 ON

5/27/97
DATE OF DEPOSIT

Thomas D Hoffman
REGISTERED REPRESENTATIVE

Thomas D Hoffman 5/27/97
SIGNATURE AND DATE OF SIGNATURE

* Box Patent Ext
Attn Hiram H. Bernstein

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APR 25 1997

Thomas D. Hoffman
Schering-Plough Corporation
Patent Department (K-6-1-1990)
2000 Galloping Hill Road
Kenilworth NJ, 07033-0530

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,634,697

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,634,697, which claims the active ingredient, ceftibuten dihydrate, of the human drug product CEDAX® (ceftibuten dihydrate- oral suspension) and a method of use of ceftibuten dihydrate, is eligible for patent term extension under 35 U.S.C. § 156, subject to the following requirement of election. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Applicant is required to elect a single patent to be extended under 35 U.S.C. § 156 and a single regulatory review period upon which the extension will be based within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to these time periods.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 27, 1996 (61 Fed. Reg. 44,068). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,179) + 1,462
= 2,052 days

Since the regulatory review period began September 28, 1988, after the patent issue date (January 6, 1987), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the limitations of 35 U.S.C. § 156(g)(6) operate to reduce the period of extension determined above. The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year exception of 35 U.S.C. § 156(c)(3) does not operate to further limit the term of the extension in the present situation because fourteen years measured from the date of approval of the approved product is after the expiration date of the patent as extended (i.e., December 20, 2009 is

after October 1, 2009).

It is noted that applicant has also filed applications for patent term extension of U.S. Patent No. 4,812,561 based upon the regulatory review of CEDAX® (ceftibuten dihydrate - capsules) and CEDAX® (oral suspension). No more than one patent may be extended for a regulatory review period of a single product. 35 U.S.C. § 156(c)(4). Furthermore, for a patent to be eligible for patent term extension, the permission for commercial marketing or use must be the first permitted commercial marketing or use of the product under the provision of law under which regulatory review occurred. See 35 U.S.C. § 156(a)(5). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the eligible patent having the earliest date of issuance unless applicant elects a different eligible patent. Therefore, only one of above-identified patent and U.S. Patent No. 4,812,561 can be extended based upon the regulatory review period of either CEDAX® (ceftibuten dihydrate - capsules) or CEDAX® (oral suspension). Furthermore, the extension can only be determined from a single regulatory review period. 35 U.S.C. 156(c). Accordingly, applicant is also required to elect a single regulatory review period upon which the extension will be based. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), an application for patent term extension in the above-identified patent will be granted based upon the regulatory review period of CEDAX® (ceftibuten dihydrate - capsules) and the above-identified application will be dismissed. If U.S. Patent No. 4,634,697 is elected based upon the regulatory review period of CEDAX® (ceftibuten dihydrate - oral suspension), the Commissioner will issue a certificate of extension, under seal, for a period of five years. Extension of time under 37 CFR 1.136(a) is NOT permitted.

If issuance of the certificate of extension occurs, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,634,697
Granted	:	January 6, 1987
Original Expiration Date	:	October 1, 2004
Applicant	:	Yoshio Hamashima
Owner of Record	:	Shionogi & Co., Ltd.
Title	:	CARBOXYALKENAMIDO-CEPHALOSPORINS
Classification	:	514/202

Product Trade Name	:	CEDAX®
Term Extended	:	Five years
Expiration Date of Extension	:	October 1, 2009

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.

Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
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Rockville, MD 20857

RE: CEDAX® (oral supension)
FDA Docket No.: 96E-0099